

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

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I	INITED	STATESOF	AMFRICA

Case:2:22-cr-20601 Judge: Borman, Paul D. MJ: Patti, Anthony P.

MJ: Patti, Anthony P. Filed: 11-10-2022 At 03:48 PM

INDI USA V. SEALED MATTER (NA)

Plaintiff,

VIO: 18 U.S.C § 1343

21 U.S.C. §§ 331(k)

21 U.S.C. § 353(b)(1) 21 U.S.C. § 333(a)(2))

18 USC § 1957

v.

ZAMAN MOHAMMED ALSHAFEY.

Defendant.

INDICTMENT

THE GRAND JURY CHARGES:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

- 1. The United States Food and Drug Administration ("FDA") was the agency of the United States charged with the responsibility of protecting the health and safety of the American public by enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA"). As part of its responsibilities, the FDA enforces the FDCA's provisions relating to the dispensing of prescription drugs in interstate commerce.
- 2. Under the FDCA, a "drug" is defined to include articles that are intended (1) for use in the diagnoses, cure, mitigation, treatment or prevention of disease in

humans, and (2) to affect the structure or function of the human body. Due to their toxicity and other potential for harmful effect, certain drugs are not considered safe for use except under the supervision of a practitioner licensed by law to administer such drugs. These drugs are known as prescription drugs. Under the FDCA, dispensing a prescription drug absent a valid prescription from a licensed practitioner is an act that results in the drug being misbranded while held for sale.

- 3. It is a prohibited act under the FDCA to do any act with respect to a drug if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce.
- 4. The FDA has approved drugs containing promethazine.
- 5. Promethazine cough syrup can have tranquilizing and euphoric effects when consumed at higher-than-recommended dose, especially when mixed with alcohol or other drugs such as fentanyl.
- 6. Promethazine cough syrup has been referred to as "Green Drink".

 Promethazine is restricted to be dispensed by prescription only per the bottle's label.
- 7. Promethazine cough syrup products vary by manufacturer in terms of viscosity, coloring, and taste. Manufacturers market their promethazine cough syrup with distinctive brand-name labeling.
- 8. Wockhardt Promethazine Syrup Plain is manufactured and distributed by Wockhardt USA LLC and has been approved by FDA as a prescription drug. The

- "Wockhardt" name is a trademark owned by Wockhardt USA LLC and registered in the principal registry in the United States Patent and Trademark Office.
- 9. Hi-Tech Promethazine Hydrochloride Oral Solution is manufactured and distributed by Hi-Tech Pharmacal (now Akorn) and has been approved by the FDA as a prescription drug. The "Hi-Tech" name and logo are owned by Hi-Tech Pharmacal (now Akorn) and Akorn retains common law trademark rights to the "Hi-Tech" name and logo.
- 10. The FDA also protects consumers by requiring that the packaging and labeling for any drug include, among other things, adequate directions for use and not include any false or misleading information. "Adequate directions for use" are directions under which a third-party vendor would recognize the type of drug being sold, or a lay person could use a drug safely and for the purposes for which it was intended.
- 11. Defendant ZAMAN MOHAMMED ALSHAFEY is a resident of Dearborn and is a licensed pharmacist in the State of Michigan. Defendant ZAMAN MOHAMMED ALSHAFEY is the owner and pharmacist in charge (PIC) of Medpro Pharmacy, located at 15580 Middlebelt Rd., Livonia, MI.

The Scheme to Defraud

12. From on or about January 2018 to on or about March 2021, in the Eastern District of Michigan and elsewhere, defendant ZAMAN MOHAMMED ALSHAFEY knowingly and willfully devised and intended to devise a scheme or

artifice to defraud his wholesale suppliers, and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises to such suppliers, and for the purpose of executing the scheme and artifice and attempting to do so, transmitted or caused to be transmitted by means of wire, radio or television communication in interstate or foreign commerce any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme and artifice, in violation of 18 U.S.C. § 1343.

Purpose of the Scheme to Defraud

13. The purpose of the scheme to defraud was for defendant ZAMAN MOHAMMED ALSHAFEY to profit from the sale of promethazine cough syrup to drug dealers without a valid prescription from a licensed practitioner by misleading wholesale distributors that the promethazine cough syrup ordered from them would be distributed to customers with a valid prescription.

Manner and Means

During all times relevant to this Indictment, the manner and means by which the scheme was sought to be accomplished include, among other things, the following:

14. ZAMAN MOHAMMED ALSHAFEY ordered thousands of pint-sized (16 ounce) bottles of promethazine cough syrup, including Wockhardt and Akorn, from multiple drug wholesalers including DTR Medical Inc, H&H Wholesale,

Amerisource Bergen, Medcare Health of New Jersey, and JM Smith.

- 15. The promethazine cough syrup ordered by ZAMAN MOHAMMED ALSHAFEY was shipped, from multiple states, including New Jersey to Medpro Pharmacy in Livonia, Michigan. Upon receipt of the promethazine, ZAMAN MOHAMMED ALSHAFEY sold the promethazine in large quantities, without valid prescriptions, to street level drug dealers for cash. The drug dealers would meet ZAMAN MOHAMMED ALSHAFEY at Medpro to purchase the promethazine.
- 16. ZAMAN MOHAMMED ALSHAFEY did not disclose to the wholesalers that he was distributing the promethazine cough syrup to drug dealers without a valid prescription.
- 17. Between January 2018, and or about March 2021, ZAMAN MOHAMMED ALSHAFEY earned millions of dollars from the sale of misbranded promethazine cough syrup without a valid prescription, through this scheme and artifice to defraud.

$\frac{\text{COUNTS 1} - 10}{\text{(Wire Fraud- 18 U.S.C § 1343)}}$

Paragraphs 1 through 17 of the General Allegations section of this Indictment are realleged and incorporated by reference as though fully set forth herein.

18. On or about each of the dates set forth below, in the Eastern District of Michigan, and elsewhere, defendant ZAMAN MOHAMMED ALSHAFEY, for

the purpose of executing the scheme described above, and attempting to do so, caused to be transmitted by means of wire communication in interstate commerce the signals and sounds described below for each count, each transmission constituting a separate count:

Count	Date	Amount	Description
	(On or About)	Paid	
1	04/18/2019	\$5,400.00	Debit card payment to DTR Medical Inc for 300 bottles of Promethazine.
2	07/10/2019	\$8,640.00	Credit card payment to H&H Wholesale for 480 bottles of Promethazine.
3	02/21/2020	\$13,200.00	Debit card payment to H&H Wholesale for 600 pint-size bottles of Promethazine.
4	07/02/2020	\$9,369.00	Debit card payment to Amerisource Bergen for 1,388 pint-size bottles of Promethazine.
5	07/17/2020	\$9,949.50	Debit card payment to Amerisource Bergen for 1,474 pint-size bottles of Promethazine.
6	10/09/2020	\$20,298.42	Credit card payment to Medcare Health of NJ for pint-size 1,086 bottles of Promethazine.
7	12/29/2020	\$9,523.50	Debit card payment to JM Smith for 350 bottles of Promethazine.
8	12/31/2020	\$10,917.60	Debit card payment to JM Smith for 430 pint- size bottles of Promethazine.
9	01/04/2021	\$13,605.00	Debit card payment to JM Smith for 500 pint- size bottles of Promethazine.
10	02/18/2021	\$12,042.98	Debit card payment to Medcare Health of NJ for 502 pint-size bottles of Promethazine.

All in violation of Title 18, United States Code, Section § 1343.

COUNTS 11 - 12

(Introduction of Misbranded Drug into Interstate Commerce-21 U.S.C. §§ 331(k), 353(b)(1), and 333(a)(2))

Paragraphs 1 through 17 of the General Allegations section of this Indictment are realleged and incorporated by reference as though fully set forth herein.

19. On or about the dates set forth below, in the Eastern District of Michigan, and elsewhere, the defendant, ZAMAN MOHAMMED ALSHAFEY, with intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce a drug, namely, promethazine cough syrup which was misbranded, pursuant to 21 USC 353(b)(1), because it was a prescription drug that was dispensed without a valid prescription:

COUNT	APPROXIMATE DATE OF TRANSACTION	AMOUNT	PURCHASER
11	08/04/2020	12 pint-size bottles of promethazine	Individual #1
12	03/11/21	228 pint-size bottles of promethazine	Individual #1

All in violation of Title 21, United States Code, Sections 331(k), 333(a)(2).

COUNTS 13 - 20 (Engaging In Monetary Transactions Exceeding \$10,000 in Criminally Derived Property- 18 USC § 1957)

Paragraphs 1 through 17 of the General Allegations of the Indictment are realleged and incorporated by reference as though fully set forth herein.

20. On or about the dates set forth below, in the Eastern District of Michigan, and elsewhere, defendant ZAMAN ALSHAFEY did knowingly engage or attempt to engage in the following monetary transactions, by and through a financial institution, affecting interstate or foreign commerce, in criminally derived property of a value greater than \$10,000, that is the payments to pharmaceutical supply companies, transfer of funds, purchase of vehicles, and payments on credit card accounts, such property having been derived from a specified unlawful activity, specifically wire fraud:

COUNT	DATE (On or about)	TRANSFER AMOUNT
13	01/17/2020	\$10,560.00 to H and H Wholesale
14	02/21/2020	\$13,200.00 H and H Wholesale
15	07/20/2020	\$10, 240. 10 to Amerisource Bergen
16	07/27/2020	\$24, 644.07 to Amerisource Bergen
17	08/28/2020	21, 960.00 to MedCare Health of NJ

COUNT	DATE (On or about)	TRANSFER AMOUNT
18	09/03/2020	\$11, 808.00 to MedCare Health of NJ
19	01/20/2021	\$14,495.00 to JM Smith Corporation
20	01/25/2021	\$17,394.00 to JM Smith Corporation

All in violation of Title, 18, United States Code, Section 1957.

FORFEITURE ALLEGATIONS (Criminal Forfeiture - 18 U.S.C. §§ 981(a)(1)(C), 982(a)(1), (a)(7), and 28 U.S.C. § 2461(c))

The allegations contained in this Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(1), (a)(7) and Title 28, United States Code, Section 2461(c).

Pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), upon conviction of the offenses set forth in Count 1 through 10 of the Indictment, Wire Fraud in violation of Title 18, United States Code, Section 1343, the defendant shall forfeit to the United States his interest in any property, real or personal, which constitutes or is derived from proceeds traceable to the scheme underlying his violation.

Pursuant to Title 18, United States Code, Section 982(a)(7), upon conviction of the offenses alleged in Counts 11 and 12, Introduction of Misbranded Drug into

Interstate Commerce in violation of Title 21, United States Code, Sections 331(k), 353(b)(1), and 333(a)(2) the defendant shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

Pursuant to Title 18, United States Code, Section 982(a)(1), upon conviction of the offenses in violation of Title 18, United States Code, Sections 1957, set forth in Counts 13 through 20 of the Indictment, the defendant shall forfeit to the United States of America, any property, real or personal, involved in such offense, and any property traceable to such property.

If any of the property described above, as a result of any act or omission of the defendants:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

THIS IS A TRUE BILL.

s/GRAND JURY FOREPERSON

DAWN N. ISON United States Attorney

s/REGINA R. MCCULLOUGH

Chief, Health Care Fraud Unit Assistant United States Attorney United States Attorney's Office 211 W. Fort Street, Suite 2001 Detroit, MI 48226

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Dated: November 10, 2022

Attorney signing this fo	iled: 11-10-2022 At NDI USA V. SEALE	02-49 DM		
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¹ Companion cases are matters in which it appears that (1) substantially similar evidence will be offered at trial, or (2) the same or related parties are present, and the cases arise out of the same transaction or occurrence. Cases may be companion cases even though one of them may have already been terminated.